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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,144	09/24/2003	Yossi Gross	NY-COLB 202.1-Cont-US	4554
27367 7590 04/17/2008 WESTMAN CHAMPLIN & KELLY, P.A. SUITE 1400 900 SECOND AVENUE SOUTH MINNEAPOLIS, MN 55402-3319				
EXAMINER LACYK, JOHN P				
ART UNIT		PAPER NUMBER		
3735				
MAIL DATE		DELIVERY MODE		
04/17/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/671,144

**Applicant(s)**

GROSS ET AL.

**Examiner**

John P. Lacyk

**Art Unit**

3735

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 243-274 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 249-253, 273 and 274 is/are allowed.
- 6) ☒ Claim(s) 243-248, 254-272 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 243-248, 254-272 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suda et al (5,978,712) in view of Barreras (5,807,397).

Suda et al discloses (column 1, lines 15-29) discloses that methods are well known in the art to treat incontinence by implanting electrodes that are "directly embedded into the pelvic floor muscles" to provide electrical stimulation to the muscles and that the intensity, frequency stimulation period and the like depend on cases and individual differences. Suda et al discloses the claimed methods except for specifically teaching a pulse width duration between 0.1 ms and 2 ms, although Suda et al does teach that many parameters may be varied depending on the individual and particular cases. Therefore a modification of Suda et al such that the electrical stimulation is delivered to the pelvic muscle to treat incontinence at the particular pulse width duration would have been obvious to one skilled in the art since it is considered to be a matter of routine engineering design choice to discover the optimum or workable ranges and the particular ranges must produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. Suda et al also fails to teach the stimulator device being implanted in the patient. Barreras discloses a device that is used to treat incontinence using electrodes to stimulate muscle and teaches that it is well known to implant the stimulator device in the patient. Therefore a modification of

Suda et al such that the device is actually implanted into the patient would have been obvious since Barreras teaches that it is well known in the art to fully implant the stimulator device into a patient.

3. Applicant's arguments filed 1/16/08 have been fully considered but they are not persuasive. Applicant argues that Suda et al fails to disclose implanting a stimulator device in a patient, this argument is moot in view of the above rejection. Applicant also argues that Suda et al does not teach a pulse width duration between 0.1 and 2 ms. As discussed above while Suda et al does not specifically teach the pulse width duration Suda et al does teach, page 4, lines 17-28, that many of the parameters including pulse width are "arbitrarily set by the doctor or health worker in accordance with the state of urinary incontinence of the patient". Therefore a modification of the device set the parameters to any needed level would have been obvious to one skilled in the art depending on the individual and particular state of urinary incontinence. Clearly Suda et al teaches that it would have been obvious to allow the device to be set to different parameters and the device is also used to treat urinary incontinence using electrodes implanted in the pelvic muscle, therefore to find the optimum workable ranges by routine experimentation would have been obvious to one skilled in the art as discussed above.

4. Claims 249-253 and 273-274 are allowed.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is 571-272-4728. The examiner can normally be reached on Mon-Fri, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chuck Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John P Lacy/  
Primary Examiner, Art Unit 3735

John P Lacyk  
Primary Examiner  
Art Unit 3735

J.P. Lacyk